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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/459,171	12/10/1999	LEO J. ROMANCZYK JR.	5677-085	9742

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EXAMINER

SOLOLA, TAOFIQ A

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 03/26/2003

26

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/459,171

Applicant(s)

ROMANCZYK ET AL.

Examiner

Taofiq A. Solola

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 24 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 132-140 and 194-204 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 132-140 and 194-201 is/are rejected.
- 7) ☐ Claim(s) 202-204 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>26</u> . | 6) <input type="checkbox"/> Other: _____. |

Art Unit: 1626

Claims 132-140, 194-204, are pending in this application.

Claims 1-131, 141-193, 205-224, are canceled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 132-140, are rejected under 35 U.S.C. 103(a) as being unpatentable over Clapperton et al., "Polyphenols and Cocoa Flavour," presented at the XVIth Internat. Conference of the Groupe Polyphenols, Lisbon, Portugal, vol. 16, 1992.

Applicants claim composition comprising polyphenol (procyanidin) from cocoa. In preferred embodiment the procyanidin is in dimer or oligomer, which may have 4-6 and/or 4-8 linkages. The compositions are "in the effective amounts to inhibit platelet" and are in packages having instruction on the method of use.

Determination of the scope and content of the prior art (MPEP §2141.01)

Clapperton et al., disclose composition comprising polyphenol (procyanidin) from cocoa. See the summary, page 1, paragraph 2. The procyanidins are in monomers and oligomers (table 1). The compositions are made into liquor (page 2, paragraph 4, line 2).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant invention and that of Clapperton et al. is that applicants claim composition "in the effective amounts to inhibit platelet" and packages having instruction on methods of use. Also, Clapperton et al., do not teach the type of linkages in the dimer and/or oligomers.

Finding of prima facie obviousness---rational and motivation (MPEP §2142.2413)

Art Unit: 1626

However, being in packages having instruction on methods of use is not patentable significant. Having composition in packages with instruction on methods of use is well known in the art. Also, it is well known in the art that the linkages commonly formed by dimmer and/or oligomers of procyanidins are 4-6 and/or 4-8. For example, see US 4,797,421 (cols. 2-7) and Chang et al., Prostag. Leuk. Essent, Fatty Acids (1989), Vol. 38, pages 181-188. Applicants also failed to provide evidence that the linkages in the dimmer and/or oligomers of Clapperton et al., are not 4-6 and/or 4-8. Effective amount is a limitation on method of use claim, not a composition. Therefore, the instant invention is prima facie obvious from the teaching of Clapperton et al. One of ordinary skill in the art would have known to package the composition of Clapperton et al., with instruction on methods of use at the time the invention was made. The motivation is to make additional composition comprising polyphenol (procyanidin).

Claims 194-201 rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al., Prostag. Leuk. Essent, Fatty Acids (1989), Vol. 38, pages 181-188, in view of Clapperton et al., "Polyphenols and Cocoa Flavour", presented at the XVIth Internat. Conference of the Groupe Polyphenols, Lisbon, Portugal, vol. 16, 1992.

Applicants claim a method of antiplatelet therapy comprising the use of oligomer of procyanidins, wherein the oligomer has 4-6 and/or 4-8 linkages. And is obtained from cocoa.

Determination of the scope and content of the prior art (MPEP §2141.01)

Chang et al., teach a method of antiplatelet therapy comprising the use of dimmers and oligomers of procyanidins, wherein the dimmers and oligomers have 4-6 and/or 4-8 linkages. See column 2, page 182.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Art Unit: 1626

The difference between the instant invention and that of Chang et al., is that applicants are claiming procyanidins from cocoa instead of plants by Chang et al.

Finding of prima facie obviousness--rational and motivation (MPEP §2142.2413)

However, the term "plants" embraces "cocoa," and Clapperton et al., teach procyanidin dimmers and oligomers are obtained from cocoa. Also, no matter how or where obtained the procyanidins oligomers are the same. Therefore, the instant invention is prima facie obvious from the teachings of Chang et al., and Clapperton et al. One of ordinary skill in the art would have known to extract procyanidins from cocoa at the time the invention was made. The motivation is to make additional compounds useful for antiplatelet therapy.

Applicant's arguments filed 2/24/03 have been fully considered but they are not persuasive. On the rejection of claims 132-140, applicant argues that Clapperton fails to teach the effective amount and therefore article of manufacture. This is not persuasive for reason set forth above. On the rejection of claims 194-201, applicant discloses various mechanisms of actions by procyanidins; that these mechanisms are different from that of Chang and therefore, the invention is not obvious from the teaching of Chang and Clapperton. This is not persuasive because, as written, the claims embrace the inventions of Chang and Clapperton. Applicant method is not limited to applicant to the mechanisms asserted by applicant.

Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Art Unit: 1626

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 132-140, 194-201, are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15-20, of U.S. Patent No. 6,469,053. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in US '053 are drawn to method of use of procyanidins for antiplatelet therapy while the instant claims are drawn to compositions and method of use of procyanidins for antiplatelet therapy.

Allowable Subject Matter

Claims 202-204 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 1626

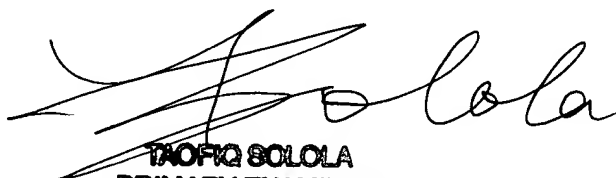
CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Taofiq A. Solola whose telephone number is (703) 308-4690. The examiner is on flexible work schedule and is generally out of the office on Wednesdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (703) 308-4537. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.


TAOFIQ SOLOLA
PRIMARY EXAMINER
Group 1626

March 23, 2003